

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

DIOMED, INC.,

Plaintiff,

v.

VASCULAR SOLUTIONS, INC.,

Defendant.

Civil Action No. 1:04-CV-10444-RGS

**DIOMED'S *MARKMAN***  
**MEMORANDUM ON CLAIM CONSTRUCTION**

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## TABLE OF CONTENTS

I.	INTRODUCTION .....	1
II.	PROCEDURAL POSTURE .....	2
III.	TECHNOLOGY AND THE PATENT-IN-SUIT .....	3
A.	Varicose Veins .....	3
B.	Treatments For Varicose Veins .....	4
C.	The Invention Of The ‘777 Patent .....	5
D.	The ‘777 Patent Claims .....	6
IV.	THE LAW OF CLAIM CONSTRUCTION .....	8
A.	In General .....	8
B.	Means-Plus-Function Language .....	10
V.	CONSTRUCTION OF ‘777 PATENT CLAIM TERMS AND PHRASES .....	11
A.	“means for emitting laser energy” .....	11
B.	“inserting means for emitting laser energy into the blood vessel” .....	13
C.	“laser emitting section” .....	13
D.	“placing said laser emitting section of said emitting means into intraluminal contact with the blood vessel” .....	14
E.	“emitting said laser energy into the blood vessel ... thereby decreasing the diameter of said blood vessel” .....	16
F.	“emptying the blood vessel” .....	18
G.	“guidance means” .....	19
VI.	CONCLUSION .....	20

Pursuant to the Court's Scheduling Order, and as provided for by the Supreme Court in Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996), Plaintiff Diomed submits this memorandum to assist the Court in its task of interpreting relevant portions of the claims of U.S. Patent No. 6,398,777 ("the '777 patent," attached as Exhibit A).

## **I. INTRODUCTION**

The '777 patent is directed to a technique for treating blood vessels with a laser. The laser energy is delivered from a fiber optic line inserted inside the vein. The laser energy damages the vein wall, causing the vein to decrease in diameter, a process that can treat conditions such as varicose veins.

Various laser treatments for blood vessels were known before the '777 patent; but it was the inventors of the '777 patent who discovered that contact between the laser emitting section of a fiber optic line and the inner wall of a blood vessel leads to a more effective and successful treatment. Accordingly, the asserted claims of the '777 patent, which are directed to a "method of treating a blood vessel using laser energy," each include the step of placing the laser emitting section of a fiber optic line "into intraluminal contact with the blood vessel." This phrase, and a few others that may require interpretation by the Court, are discussed in more detail below.

The technology of the '777 patent, summarized in Section III(C), is relatively straightforward. Much of the '777 patent's claim language is clear on its face and needs no special "construction" or re-wording by the Court. See U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1568 (Fed. Cir. 1997) (every claim term need not be affirmatively "construed" or re-worded by the court). Certain words and phrases, however, would benefit from formal Markman construction so that a factfinder can be properly informed as to their scope.

In construing these terms, the Federal Circuit teaches that the Court looks for the "ordinary meaning" of a claim term as determined from "intrinsic" evidence – i.e., the claims

themselves, the rest of the patent (including its written description or “specification”), and its prosecution history. E.g., Bell & Howell Doc. Mgmt. Prods. Co. v. Altek Sys., 132 F.3d 701, 705-06 (Fed. Cir. 1997). Extrinsic evidence (such as testimony of experts or other witnesses) may never be used to vary or contradict the terms of a claim. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584 & n.6 (Fed. Cir. 1996).<sup>1</sup> Here, the claim language can readily be understood from the intrinsic evidence (the patent specification and drawings).

## II. PROCEDURAL POSTURE

In their L.R. 16.1 Joint Schedule (which was adopted by the Court), the parties agreed that plaintiff Diomed would identify the asserted ‘777 patent claims at an early stage of the case. The Court noted at the June 10, 2004 Scheduling Conference that an early identification of the claims at issue in the case was desirable because it would enable the parties to focus solely on what was in dispute, and provide one another with early explanations of their claim construction positions. Cf. Atmel Corp. v. Information Storage Devices, Inc., 1998 U.S. Dist. Lexis 17564, \*7 (N.D. Cal. Nov. 4, 1998) (early disclosure of claims in dispute makes parties “crystallize their theories of the case early in the litigation” and “adhere to those theories”).

Accordingly, Diomed provided notice to Vascular Solutions, Inc. (“VSI”) that it would assert method claims 9-14, 16-19 and 21 of the ‘777 patent. (Exhibit B). Those are the only claims in dispute, and thus the only ones requiring construction.

The Schedule next called for the parties to exchange their proposed claim interpretations on September 1, 2004. The parties did so. (Exhibits C, D). Diomed’s claim construction position has not changed since that date. In a telephonic conversation held on September 20, 2004, however, VSI indicated that some of its claim construction positions had changed.

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<sup>1</sup> Dictionary definitions may be used to aid claim construction so long as the dictionary definition does not contradict any definition found in the patent. Id. at 1583.

Inasmuch as VSI has not provided any modified claim construction in writing, Diomed relies for present purposes upon VSI's original statement and will rebut any purported modification thereto at the appropriate time.

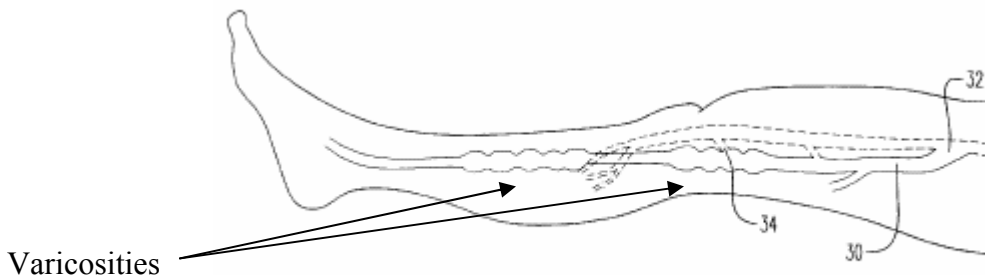
The parties' respective claim interpretation proposals parse the disputed claim language somewhat differently. This is not uncommon. *E.g., Nonin Medical, Inc. v. BCI, Inc.*, 2004 U.S. Dist. Lexis 3824, \*7-8 (D. Minn. Mar. 8, 2004) (parties advanced "overlapping" claim interpretation proposals). As required by the Court's schedule, this brief will explain Diomed's proposed claim construction. A subsequent brief (due on October 22, 2004) will rebut whatever arguments VSI may make that are inconsistent with these proposed constructions.

### III. THE TECHNOLOGY OF THE PATENT-IN-SUIT

A brief description of the anatomy and medical history underlying the '777 patent may assist the Court in its claim construction.

#### A. Varicose Veins

As described in the '777 patent, certain veins, particularly in the leg, can become swollen or "varicose." For example, as shown in Fig. 1, the greater saphenous vein 30 can become varicose due to an incompetent valve 32 that does not close properly, causing blood to run backwards ("reflux") and pool in the leg. (Col. 4, lines 22-29).



**FIG. 1**

The same can happen to the lesser saphenous vein (Fig. 9; Col. 5, lines 58-61) and other miscellaneous veins (Fig. 15; Col. 6, lines 26-32). In addition to reflux at a valve, other causes

of varicosity can include incompetent “perforators” (blood vessels connecting a vein to other portions of the venous system). (Id.).

Besides being unsightly, varicose veins can cause medical problems such as blood clots, leg ulcers and infection. Accordingly, while varicose veins need not always be treated, many patients do seek treatment for either esthetic or medical reasons, or both.

**B. Treatments For Varicose Veins**

As explained in the Background section of the ‘777 patent, traditional treatments for varicose veins include ligation and stripping (a surgical procedure involving physical removal of the vein from the leg) and sclerotherapy (introduction of an irritant chemical into the vein to cause the vein to close). (Col. 1, lines 26-60).

Each of the traditional treatments had drawbacks. Ligation and stripping, for example, requires general anesthesia and involves risk of bleeding, infection, and a prolonged recovery period, among other issues. (Col. 1, lines 37-47). Although less invasive than ligation and stripping, sclerotherapy has an unsatisfactory success rate (studies show recurrence in 30% to 70% of patients after five years). (Col. 1, lines 27-36).

Most laser techniques for treating vein disorders that were known before the ‘777 patent involved irradiating the outer surface of the skin with laser energy. The beam would penetrate the skin, be absorbed by the blood inside the blood vessel, and cause coagulation of the blood. (Col. 1, lines 16-19). As the ‘777 patent explains (at Col. 1, lines 20-25):

Larger varicose veins are located deeper in the soft tissues. Such veins have not been successfully treated with laser techniques. It is believed that treating such larger veins with laser energy delivered from the surface would require higher powers that could lead to increased side effects including scarring and skin hyper- or hypopigmentation.

### C. The Invention Of The ‘777 Patent

The ‘777 patent describes a procedure for laser treatment of veins, from within the vein, in a manner that causes the vein to shrink or collapse. The inventors of the ‘777 patent discovered that damaging the wall of the blood vessel is superior to clotting of the blood within the vessel, because techniques that rely on clotting do not effectively treat blood vessels of larger diameter. (Col. 2, lines 1-6, 57-60). Delivering laser energy from within the blood vessel rather than from outside the skin has the added benefit of minimizing the risk of harm to the skin and intervening tissues. (Col. 2, lines 54-57).

The invention of the ‘777 patent is described in the patent specification, which provides three examples of the procedure’s use. By way of illustration, one method – though by no means the only one covered by the patent – treats the greater saphenous vein in the upper leg as follows:

- The treatment areas is anesthetized with a local anesthetic.
- Access is gained to the blood vessel, typically by insertion of a standard entry device such as an angiocatheter or by incision and insertion of the fiber.
- A fiber optic line with an exposed portion such as an uncoated tip (for emission of laser energy) is inserted into the interior lumen of the vessel. The non-emitting portion of the fiber optic line is coated with a known substance for mechanical protection and to prevent emission of the laser energy in undesired locations.
- The fiber optic line is advanced to the desired portion of the vessel, in this case just shy of the incompetent valve. (Positioning of the fiber optic line may be achieved, for example, with an ultrasound imager or with a visible aiming beam.<sup>2</sup>)
- The laser is fired through the fiber optic line as the fiber optic line is withdrawn within and along the vessel lumen. The primary wavelength of the laser light is between 500 and 1100 nanometers.
- Contact occurs between the emitting section of the fiber and the wall of the blood vessel, facilitating the desired transfer of laser energy to the vessel wall. Contact may result from any number of a variety of factors, individually or in combination – what actually brings about contact is of no moment. The patent discloses, without limitation, several techniques for ensuring contact between the emitting section and the inner vein wall (e.g., lifting the patient’s leg to drain blood from the vessel, or applying external pressure to it).

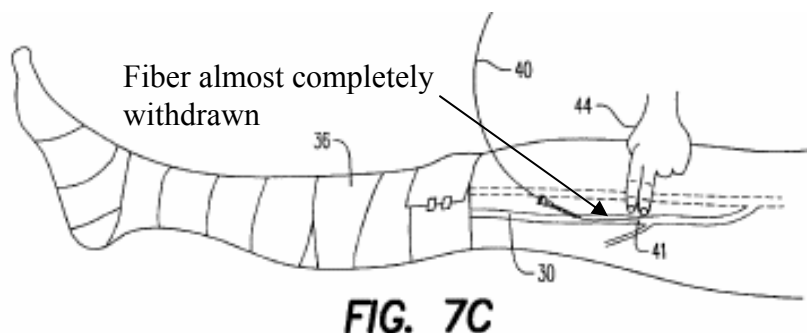
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<sup>2</sup> The laser energy itself is not in the visible spectrum, so a separate aiming beam is provided.

- As the fiber is withdrawn, sufficient laser energy is delivered to the wall of the vessel to lead to a decrease in the diameter thereof.

(Col. 2, line 21 – Col. 3, line 57).

Figures 3A through 7C illustrate this procedure, with Figure 7C reproduced here:



The '777 patent provides two additional examples of the procedure, one for the lesser saphenous vein lower in the leg (Figs. 9-14; Col. 5, line 58 – Col. 6, line 25) and one for other miscellaneous veins (Figs. 15-20; Col. 6, lines 26-57). The procedure described in these examples is similar to that described with respect to the greater saphenous vein; but again, nothing in the patent limits the claims to the particular procedure described here, nor does the patent require any particular mechanism for inducing contact, or any particular duration for the burst of the laser energy as long as clinical benefit occurs.

#### **D. The '777 Patent Claims**

The claims of a patent describe the boundaries of the patentee's right to exclude others from use of the claimed method (or product, but this case involves method claims). Having described the patented procedure generally above, we turn now to the asserted claims. There are two independent asserted claims (9 and 21). The remainder of the asserted claims (10-14 and 16-19) depend, directly or indirectly, from independent claim 9 and therefore incorporate all the limitations of claim 9. See 35 U.S.C. § 112, ¶ 4 ("A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.").



As noted previously, much of the language in the claims of the '777 patent is clear on its face. Those words and phrases in the disputed claims that Diomed believes would benefit from formal Markman construction are shown in bold:

<p>9. A method of treating a blood vessel using laser energy, comprising the steps of:  inserting <b>means for emitting laser energy</b> into the blood vessel at a puncture site, wherein said emitting means has a <b>laser emitting section</b>;  <b>placing</b> said laser emitting section of said emitting means <b>into intraluminal contact with the blood vessel</b> at a treatment site; and  <b>emitting</b> said laser energy into the blood vessel through said laser emitting section of said emitting means, <b>thereby decreasing the diameter of said blood vessel</b>.</p>
<p>10. The method of claim 9, further comprising <b>emptying the blood vessel</b> prior to emitting said laser energy.</p>
<p>11. The method of claim 9, wherein said emitting means is inserted into the blood vessel through the use of an angiocatheter.</p>
<p>12. The method of claim 9, wherein said emitting means is about 200 microns to about 600 microns in diameter.</p>
<p>13. The method of claim 9, wherein said emitting means is a fiber optic line.</p>
<p>14. The method of claim 9, wherein said laser emitting section of said emitting means is located at a tip of said emitting means.</p>
<p>16. The method of claim 14, wherein said tip of said emitting means is located at the treatment site through the use of a <b>guidance means</b>.</p>
<p>17. The method of claim 9, further comprising applying compression externally to the blood vessel prior to applying said laser energy, thereby ensuring contact of said tip of said emitting means with the blood vessel.</p>
<p>18. The method of claim 9, wherein said laser energy is applied in the range of about 500 nanometers to about 1100 nanometers.</p>
<p>19. The method of claim 9, wherein said laser energy is delivered in bursts.</p>
<p>21. A method of treating a blood vessel using laser energy, comprising the steps of:  inserting <b>means for emitting laser energy</b> into the blood vessel at a puncture site, wherein said emitting means has a <b>laser emitting section</b>;  <b>placing</b> said laser emitting section of said emitting means <b>into intraluminal contact</b></p>

**with the blood vessel** at a treatment site;  
**emptying the blood vessel**; and  
**emitting** said laser energy into the blood vessel through said laser emitting section of said emitting means, **thereby decreasing the diameter of said blood vessel**.

The interpretations that Diomed believes are appropriate for these bolded terms are discussed in Section V below, after a brief overview of the law of claim construction.

#### IV. THE LAW OF CLAIM CONSTRUCTION

##### A. In General

The scope of a patent is defined by its “claims,” which appear as numbered paragraphs at the end of the patent.

In order to evaluate the core issues in a patent case (e.g., validity of the patent and infringement of the patent by the accused product or method), one must first resolve any ambiguities in the meaning of the claims. Such interpretation (or “construction”) of the claims is a matter of law for the Court. Markman, 517 U.S. 370.

Often, many of the words and phrases used in a patent claim are sufficiently straightforward that no formal “interpretation” is necessary to understand them.

The *Markman* decisions do not hold that the trial judge must repeat or restate every claim term in order to comply with the ruling that claim construction is for the court. Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and *when necessary* to explain what the patentee covered by the claims, for use in the determination of infringement. *It is not an obligatory exercise in redundancy.*

U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1568 (Fed. Cir. 1997) (emphasis added).

Thus, the Court need not add complexity or needlessly expand upon claim language that has, and may properly be attributed, an ordinary meaning.

Other words or phrases, however, may require formal Markman construction to ensure that the claim is accorded its legally proper meaning, namely the meaning that would be given it

by one of skill in the relevant art reading the claim in view of the patent specification. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582-83 (Fed. Cir. 1996) (en banc).

Interpretation of a patent claim begins with the claim language itself. After examining the language of a claim, the Court looks to the “intrinsic” record – i.e., the patent specification, drawings and file history (the record of proceedings before the Patent Office) – to determine the meaning of the claim language in context. Id. Although claims are to be read in light of the patent specification, limitations may *not* be read from the specification into the claims. Comark Comm’ns, Inc. v. Harris Corp., 156 F.3d 1182, 1186 (Fed. Cir. 1998) (“[W]hile claims are to be interpreted in light of the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims.”). Patent claim language is thus to be given the broadest scope its language allows, absent contrary definition in the patent or prosecution history. See Home Diagnostics, Inc. v. Lifescan, Inc., 2004 WL 1925613 (Fed. Cir. 2004) (“Absent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language.”).

The Court may also compare the language of one claim to another, pursuant to a canon of claim construction known as “claim differentiation.” This canon states that because dependent claims incorporate by reference the limitations of the independent claims from which they depend, see 35 U.S.C. § 112, ¶ 4, an independent claim is presumed to be broader than a claim depending from it. Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 910 (Fed. Cir. 2004) (“[T]he presence of a dependent claim that adds a particular limitation raises a presumption that the limitation in question is not found in the independent claim.”).

Although the Court may examine “extrinsic” evidence (such as expert testimony) for background purposes, such extrinsic evidence may never be used to vary or contradict the words of a claim. Markman v. Westview Instruments, Inc., 52 F.3d 967, 981 (Fed. Cir. 1995), aff’d,

517 U.S. 370 (1996) (“Extrinsic evidence is to be used for the court’s understanding of the patent, not for the purpose of varying or contradicting the terms of the claims.”).<sup>3</sup>

## **B. Means-Plus-Function Language**

The Patent Statute permits patentees to write portions of their claims in what is called “means-plus-function” language, which recites a function to be performed rather than definite structure or materials for performing that function. Such claim limitations are governed by 35 U.S.C. § 112, ¶ 6, which provides:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Before analyzing what appears to be a means-plus-function claim limitation, the Court must first assure itself that such a limitation is in fact at issue. A claim limitation that actually uses the word “means” invokes a rebuttable presumption that the inventor used the term advisedly to invoke the statutory mandate of § 112, ¶ 6. Altiris, Inc. v. Symantec Corp., 318 F.3d 1363, 1375 (Fed. Cir. 2003). This presumption may be rebutted if the limitation recites sufficiently definite structure for performing the function. Id.

If the claim limitation is subject to § 112, ¶ 6, then to construe it the Court must identify the claimed function to be performed, and the structure(s) in the specification that perform that function (the “corresponding structure”). The limitation is interpreted to cover any structure that (1) performs the identical function recited in the limitation; and (2) is identical or “equivalent” to

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<sup>3</sup> Some Federal Circuit cases have referred to extrinsic dictionary definitions as having a “special place” in the claim construction analysis. The continuing validity of this line of cases is in question, however, because the court is reconsidering, *en banc*, whether reliance upon dictionary definitions in construing patent claims should continue. See Phillips v. AWH Corp., 376 F.3d 1382, 1383 (*en banc* question: “Is the public notice function of patent claims better served by referencing primarily to technical and general purpose dictionaries and similar sources to interpret a claim term or by looking primarily to the patentee’s use of the term in the specification?”). Nothing in Diomed’s proposed claim construction, however, turns on the outcome of this issue. Should such an issue arise from VSI’s claim construction briefing, Diomed will address it in its response.

the corresponding structure disclosed in the patent specification. E.g., Odetics, Inc. v. Storage Tech. Corp., 185 F.3d 1259, 1267 (Fed. Cir. 1999).

## V. CONSTRUCTION OF ‘777 PATENT CLAIM TERMS AND PHRASES

The above principles help determine how to construe relevant limitations of the ‘777 patent claims. As noted above, many of the words and phrases of the ‘777 patent claims do not require any formal Markman treatment by the Court. Such terms should be given their plain and ordinary meaning, without re-definition or expression in alternative terminology. In other instances, however, resort to the ‘777 patent specification is helpful in establishing the proper interpretation of particular terms in the patent.<sup>4</sup> Those instances are discussed below.

### A. “means for emitting laser energy”

Independent claims 9 and 21 (and, by reference, the dependent claims depending therefrom) each recite a “means for emitting laser energy” that is inserted into the blood vessel to carry laser energy to the appropriate location(s) within the vessel. Use of the word “means” invokes a presumption that this phrase is to be construed as a § 112, ¶ 6 means-plus-function limitation. Because no structure is recited in the claim for “emitting laser energy,” the presumption is not rebutted. Altiris, 318 F.3d at 1375. Accordingly, this is a means-plus-function phrase, and must be construed to cover the corresponding structure described in the specification and any equivalents thereof.<sup>5</sup>

The next step in the analysis of a means-plus-function limitation is to identify the claimed function to be performed, and the structure disclosed in the specification for performing that function. Odetics, 185 F.3d at 1267. The “function to be performed” is “emitting laser energy.”

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<sup>4</sup> While the file history of a patent can, in some cases, also shed light on the meaning or scope of claim terms, no positions or arguments were taken during the prosecution of the ‘777 patent that should influence the construction of the asserted claims.

<sup>5</sup> VSI appears to agree that this phrase should be interpreted under § 112, ¶ 6.

The structure disclosed in the specification for performing that function is a fiber optic line that carries and delivers the laser energy, the fiber having an exposed portion for allowing the laser energy to be emitted from the otherwise coated fiber:

- “[L]aser energy about 500 nanometers to about 1100 nanometers in wavelength is delivered in bursts *through fiber optic line 40 into the vein wall.*” (Col. 5, lines 17-19) (emphasis added).
- “While laser energy is delivered in bursts *through the fiber optic line 40*, the fiber optic line is incrementally withdrawn from the greater saphenous vein.” (Col. 5, lines 24-26) (emphasis added).
- “Fiber optic line 40 has a tip 41 that is uncoated so as to allow emittance of laser energy. The remainder of fiber optic line 40 can be coated with various substances known to the art. The coated portion of fiber optic line 40 will not emit laser energy.” (Col. 4, lines 52-56).

The fiber optic line is described, and shown in the Figures, as a stand-alone fiber that is not obstructed, such that the light-emitting exposed section of the fiber can contact the inner wall of the vein (which, as noted above, is important to success of the procedure).

The patent specification does not limit the performance of the stated function (“emitting laser energy”) to any specific type of fiber optic line. For example, the specification explains that the fiber can have a range of diameters, from “about 200 microns to about 600 microns.” (Col. 4, line 65). Likewise, the fiber tip “is preferably rounded in shape, although other shapes are contemplated.” (Col. 4, lines 59-60).

All of the fibers disclosed in the specification, regardless of diameter or tip shape, perform the function of “emitting laser energy.” Accordingly, the “means for emitting laser energy” must be interpreted to cover all such “corresponding structure” in the patent specification, and all equivalents thereof. It cannot be limited to a particular one of the configurations disclosed. See, e.g., Overhead Door Corp. v. Chamberlain Group, Inc., 194 F.3d 1261, 1273 (Fed. Cir. 1999) (“The district court erred in ruling that only the mechanical switch in Figure 2 is ‘corresponding structure’ for the claimed ‘switch means.’ ‘Switch means,’ when

properly construed, also covers the software-based embodiment described in Figure 3.”).<sup>6</sup>

Diomed thus requests that the phrase “means for emitting laser energy” be interpreted to mean:

any of the stand-alone fiber optic lines disclosed in the ‘777 patent specification and equivalents thereof (hereinafter “fiber optic line”)

**B. “inserting means for emitting laser energy into the blood vessel”**

Claims 9 and 21 recite the step of “inserting means for emitting laser energy into the blood vessel.” This step is straightforward and is described in the specification as follows:

- “[I]n a preferred embodiment, fiber optic line 40 is introduced *into the vein lumen* via angiocatheter 38.” (Col. 4, lines 50-52) (emphasis added).
- “It is a further object of the present invention to provide such a method that introduces a fiber optic line *into the vein lumen* to deliver intraluminal laser energy.” (Col. 3, lines 6-8) (emphasis added).

Accordingly, Diomed requests that the phrase “inserting means for emitting laser energy into the blood vessel” in claims 9 and 21 be interpreted to mean:

inserting the fiber optic line [defined above] into the interior lumen of the blood vessel

**C. “laser emitting section”**

Claims 9 and 21 each explain further that the fiber optic line has a “laser emitting section” from which the laser energy is discharged.

The specification explains that this is an exposed portion (i.e., free of the cladding that coats optical fibers): “Fiber optic line 40 has a tip 41 that is *uncoated so as to allow emittance of*

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<sup>6</sup> Not only does means-plus-function case law dictate that the claim must be interpreted to cover *all* corresponding structures for performing the recited function, but the doctrine of claim differentiation has the same effect here. Because dependent claim 15 is limited to a “means for emitting laser energy” that has a rounded tip, the “means for emitting laser energy” recited in independent claim 9 (from which claim 15 depends, through claim 14) cannot be construed as being limited to having a rounded tip. Otherwise, the independent claim would collapse into the dependent claim, in violation of the doctrine of claim differentiation. See Liebel-Flarsheim, 358 F.3d at 910.

*laser energy*. The remainder of [the] fiber optic line 40 can be coated . . . and [that portion] will not emit laser energy.” (Col. 4, lines 52-56) (emphasis added). This is not a means-plus-function claim; it does not require the laser-emitting section to be located at any particular part of the fiber. This limitation means any uncoated portion of the fiber through which laser is emitted.

Although the preferred embodiment shows the laser emitting section at the fiber “tip,” that location is not a limitation to the claim language. It would be error to read a limitation from a preferred embodiment into the scope of a claim. See, e.g., Laitram Corp. v. Cambridge Wire Cloth Co., 863 F.2d 855, 865 (Fed. Cir. 1988) (“References to a preferred embodiment . . . are not claim limitations.”); Comark, 156 F.3d at 1187 (prohibiting use of language from a preferred embodiment as a limitation on a claim).

The doctrine of claim differentiation further establishes that the “laser emitting section” need not be located at the tip of the fiber. Because dependent claim 14 specifies that the laser emitting section is located at the tip, independent claim 9 (from which claim 14 depends) necessarily encompasses other arrangements. The same is true for the “laser emitting section” in claim 21, because like words and phrases are to be interpreted consistently across the claims of a patent. Fin Control Sys. v. OAM, Inc., 265 F.3d 1311, 1318 (Fed. Cir. 2001).

Accordingly, Diomed requests the following interpretation for “laser emitting section”:

an exposed portion of the fiber optic line [defined above] from which laser energy is emitted (e.g., the bare, uncoated tip of the fiber optic line) (hereinafter “bare tip”)

**D. “placing said laser emitting section of said emitting means into intraluminal contact with the blood vessel”**

Claims 9 and 21 next recite that the laser emitting section is placed in intraluminal contact with the blood vessel. This is (as noted above) an important step to achieving effective treatment. The Summary of the Invention explains that “It is a further object of the present



invention to provide such a method ... with direct contact of the tip of the fiber optic line with the vein wall.” (Col. 3, lines 6-10). Contact may occur at any number of points as the laser emitting section is moved within and along the vessel lumen. For example, “fiber optic line 40 ... simultaneously delivers laser energy to and is withdrawn from greater saphenous vein 30.” (Col. 5, lines 45-48). Notably, the Summary of the Invention states only that contact is needed – there is no requirement that contact must be achieved in any particular way.

In the preferred embodiment, some examples are described for ways to help ensure that contact will occur. For example, blood may be drained from the vein and/or pressure may be applied to the vein. E.g., Col. 6, lines 11-13 (“The drainage of blood is important to insure direct contact of the vessel walls with tip 41 during delivery of laser energy.”); Col. 6, lines 43-46 (“[V]ein 54 is emptied of blood and compressed to insure direct contact of the vessel walls with tip 41 during delivery of laser energy.”). Contact can of course be achieved (and, in practice, is often achieved) in other ways. The patent does not limit the means by which this may occur.

The dependent claims of the ‘777 patent make clear that the “contact” limitation of independent claims 9 and 21 does not require drainage of blood or external pressure. Specifically, dependent claim 10 recites “emptying the blood vessel,” and dependent claim 17 recites that contact can be “ensured” with the application of external compression, such that the “contact” limitation of independent claim 9 does not require either emptying or compression. Liebel-Flarsheim, 358 F.3d at 910. The same is true for the “contact” limitation of claim 21, because (as noted above) like phrases in patent claims receive the same interpretation. Fin Control, 265 F.3d at 1318.<sup>7</sup>

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<sup>7</sup> Indeed, claim 21 itself recites the “emptying step” explicitly, a recitation that would be superfluous if the “contact” step already included emptying. See Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1187 (Fed. Cir. 1998) (finding a violation of the doctrine of claim differentiation when a proposed construction would render another claim superfluous).

In summary, the limitation “placing said laser emitting section of said emitting means into intraluminal contact with the blood vessel,” which requires contact as the laser emitting section is moved within and along the vessel lumen (without specifying how that is to be achieved), should be interpreted as follows:

contacting the bare tip [defined above] and the inner wall of the vessel as the fiber optic line is moved within and along the vessel lumen

**E. “emitting said laser energy into the blood vessel ...  
thereby decreasing the diameter of said blood vessel”**

As the “thereby” clause in this phrase indicates, sufficient laser energy must be emitted to cause vessel wall tissue damage leading to a decrease in the diameter of the blood vessel (which means, in short, that the claim covers a technique that provides some clinical benefit). As noted above, this emphasis on vein wall damage distinguishes the invention of the ‘777 patent from earlier laser techniques, which used laser energy to coagulate blood within the vessel (rather than damaging the tissue of the vessel itself). Specifically, the ‘777 patent explains that the damage inflicted by the intraluminal delivery of laser energy causes fibrosis of the vessel wall, and ultimately leads to a decrease in the diameter of the blood vessel:

- “It is yet another object of the present invention to provide such a method that avoids blood clot formation and maximizes vein wall damage.” (Col. 3, lines 10-12).
- “By delivering laser energy intraluminally, the entire thickness of the vein wall is damaged. This results in fibrosis of the vein and a decrease in the diameter of the varicosity. Preferably, the vein wall will be damaged to the extent that the subsequent fibrosis causes the vein to collapse.” (Col. 3, lines 18-22).
- “This method insures damage to the entire thickness of the vein wall of greater saphenous vein 30, ultimately resulting in fibrosis of the vein wall. Fibrosis of the vein wall leads to a decrease in the diameter of the vein. The amount of fibrosis in the vein wall is determined by the amount of laser energy delivered thereto. Preferably, the method will damage the vein wall to an extent that the subsequent fibrosis causes the vein to collapse.” (Col. 5, lines 27-35).

Although the claim language requires emission of laser energy through an emitting section that “contacts” the vein wall (see previous limitation discussed in Section V(D)), there is no requirement in the “emitting” limitation (or elsewhere) that such contact be maintained for any particular length of time or at any particular number of locations in the vessel. Rather, the only requirement is that the emission-during-contact be sufficient to have a clinically significant effect, i.e., satisfying the claim limitation “thereby decreasing the diameter of the vein.”

In short, the required emission, in the context of the asserted claims, is *qualitative* (referring to clinical efficacy), not *quantitative*. The patent specification makes this clear when it emphasizes that the duration and frequency of contact leading to the desired narrowing of the vessel may be varied for a particular vessel and nonetheless result in a therapeutically effective treatment. See, e.g., Col. 6, lines 16-18 (disclosing laser bursts from about 0.2 to about 10 seconds in duration) and Col. 5, lines 49-51 (noting that power and burst duration may be adjusted during the procedure based upon clinical observations and obtained results). Consequently, a proper interpretation of the emitting limitation should *not* require any particular duration of emission-during-contact nor numerical quantification of occurrences of touching between the inner vessel wall and the emitting section. “When numerical ranges are described in the specification, they are not constructed as limits but as examples.” Finnsugar Bioproducts, Inc. v. Amalgamated Sugar Co., 1999 WL 675303, \*11 (N.D. Ill. 1999). See also Applera Corp. v. MJ Research Inc., 292 F. Supp. 2d 348, 369 (D. Conn. 2003) (“Defendants’ proposal to import precise numerical limitations from the preferred embodiments of the claimed invention is inappropriate. Reading numerical precision into imprecise claim terms is usually incorrect.”).

In short, the “emitting” limitation should be construed simply to mean the step of delivering laser energy at enough points of contact between the emitting section and the inner wall along a vessel being treated to cause a reduction in vessel diameter. See Edwards Systems

Technology, Inc. v. Digital Control Systems, Inc., 99 Fed. Appx. 911, 918 (Fed. Cir. 2004) (holding that a limitation described in qualitative terms, relating to its effect, should be so construed rather than limited to a numerical range).

Accordingly, Diomed proposes that the language “emitting said laser energy into the blood vessel through said laser emitting section of said emitting means, thereby decreasing the diameter of said blood vessel” be interpreted as follows:

emitting sufficient laser energy at the bare tip of the fiber optic line to cause vessel wall tissue damage (e.g., fibrosis) to lead to a decrease in the diameter of the blood vessel

**F. “emptying the blood vessel”**

The step “emptying the blood vessel” is recited in dependent claim 10 and independent claim 21. In the context of the patented procedure, the ‘777 patent specification explains that this step can be performed by raising the patient’s leg, applying pressure, or both. See Col. 4, lines 36-38 (“Compression bandage 36 facilitates emptying of the superficial venous system of leg 10.”); Col. 5, lines 7-10 (“Then, the patient is placed [with] leg 10 elevated. In this position, saphenofemoral junction 32 is compressed, preferably by a hand 44 or ultrasound imager 42, to empty greater saphenous vein 30.”). The purpose of the “emptying” step is to enable the laser emitting section of the fiber to “make[] direct contact with the vein wall.” (Col. 5, lines 16-17).

Neither the claim limitation nor the specification require that the “emptying” must be total. It is hard to imagine a scenario in which every last blood cell could be removed from within a living human blood vessel such that the vessel would be *completely* empty. It is improper to read into a claim a requirement that the act described be absolute, total, or complete when nothing in the claim language or specification so provides. See Bell Communications Research, Inc. v. Fore Systems, Inc., 62 Fed. Appx. 951, 955 (Fed. Cir. 2003) (claimed method

for generating information packets and then “inserting packets ‘into the empty payload fields’” did not require that empty frames be *completely* generated); Bell Communications Research, Inc. v. Fore Systems, Inc., 2003 WL 22295442 (D.Del 2003) (on remand) (“empty payload field” does not mean completely empty; “that the payload field could contain nothing [is] illogical”); Kumar v. Ovonic Battery Co., 351 F.3d 1364, 1369 (Fed. Cir. 2003) (noting that it is improper to read limitations like “totally” or “completely” into claim language when such limitations are not present, and holding that the term “random” “can . . . mean completely random or partially random”).

Indeed, the ordinary meaning of “emptying” is not so draconian as to mean complete removal of everything. One can be “filling” one’s car with gas even if one stops before a full tank. Likewise, one can be “emptying” one’s swimming pool (or glass of water) even if one stops while the pool (or glass) is still half full. In short, the ordinary meaning of the term “emptying” – the required starting point for claim construction – does not require that *all* of the contents be removed. “Emptying” is a process, not a full and finished act implying that nothing at all is left behind. See Bell Communications, 62 Fed. Appx. at 955 (Federal Circuit noting that “both ‘generating’ and ‘filling’ are continuous processes.... [I]t makes little sense to speak of the generating process being ‘complete’ before filling begins”). Accordingly, Diomed proposes that this limitation be interpreted to mean:

removing some or all of the blood from the blood vessel
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**G. “guidance means”**

The “guidance means” recitation in dependent claim 16 is presumptively to be construed as a § 112, ¶ 6 means-plus-function limitation because it uses the word “means.” Because no

structure is recited in the claim for locating the tip of the fiber optic line, the presumption is not rebutted. Altiris, 318 F.3d at 1375. Accordingly, this is a means-plus-function limitation.

Having identified the function to be performed by the guidance means in claim 16 (locating the tip of the fiber optic line), the next step is to identify the structure disclosed in the specification for performing that function:

“Positioning of tip 41 is preferably accomplished by *emitting laser energy in the visible spectrum* through tip 41. This visible spectrum energy can be seen through the skin and may be emitted concurrently with laser energy in other wavelengths. Alternatively, *a traditional ultrasound imager*, shown generally as 42, may be used.”

(Col. 5, line 66 – Col. 6, line 5).

The “guidance means” of claim 16 should be interpreted to cover all such “corresponding structure” in the ‘777 patent specification and equivalents thereof. Accordingly, Diomed proposes that “guidance means” be interpreted to mean:

an aiming beam or an ultrasound imager and equivalents thereof
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## VI. CONCLUSION

For the above reasons, the claim interpretations proposed by Diomed should be adopted.

Respectfully submitted,

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**Appendix A – Claim Construction Proposed By Diomed**

Claim(s)	Limitation	Construction
9, 21	means for emitting laser energy	any of the stand-alone fiber optic lines disclosed in the '777 patent specification and equivalents thereof (hereinafter "fiber optic line")
9, 21	inserting means for emitting laser energy into the blood vessel	inserting the fiber optic line into the interior lumen of the blood vessel
9, 21	laser emitting section	the exposed portion of the fiber optic line from which laser energy is emitted (e.g., the bare, uncoated tip of the fiber optic line) (hereinafter "bare tip")
9, 21	placing said laser emitting section of said emitting means into intraluminal contact with the blood vessel	contacting the bare tip and the inner wall of the vessel as the fiber optic line is moved within and along the vessel lumen
9, 21	emitting said laser energy into the blood vessel ... thereby decreasing the diameter of said blood vessel	emitting sufficient laser energy at the bare tip of the fiber optic line to cause vessel wall tissue damage (e.g., fibrosis) to lead to a decrease in the diameter of the blood vessel
10, 21	emptying the blood vessel	removing some or all of the blood from the blood vessel
16	guidance means	an aiming beam or an ultrasound imager and equivalents thereof